

Remarks

Upon entry of the amendment, claims 1, 3, 4 and 11-35 will be pending in the application. Claims 2, 5-10 and 36-46 are cancelled as drawn to non-elected subject matter. Applicants reserve the right to pursue the subject matter of all cancelled claims in a continuing application or applications.

Applicants have amended the application so that it no longer claims priority to parent applications USSN 08/495,724, filed June 27, 1995 and 08/892,407, filed July 15, 1997, and to include updated information on the status of parent application USSN 09/179,026,.

Applicants have amended the title as suggested by the Examiner and have amended the specification to recite the new address noted in the Office Action for the ATCC.

Rejection under 35 USC 112, first paragraph

Claims 1-4 and 11-35 are rejected for overbreadth. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1, from which the remaining claims subject to the rejection depend, has been amended so that it is drawn to a method of treating mucositis. As noted by the Examiner (page 3, paragraph 7), the specification is enabling for a method of treating mucositis with IL-11 (see pages 20-24 and 25-26, Examples 2 and 4). Thus, this rejection can be withdrawn.

Rejections under 35 USC 102(b)

Claims 1, 11-16, 18-19, 21-27, 29-30 and 34 are rejected as being anticipated by U.S. Patent No. 5,215,895 (hereinafter, "the '895 patent"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1 has been amended to incorporate the subject matter of claim 2, which is not subject to the rejection. Therefore, claim 1 is not described by the '895 patent. All the remaining claims subject to the rejection depend from claim 1. Therefore, these remaining claims are also not described by the '895 patent.

Claims 1-4 and 11-35 are rejected as being anticipated by Keith *et al.*, (Stem Cells, 12(suppl 1):79-90, 1994) (hereinafter, "Keith"). Claim 2 has been cancelled. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1, from which the remaining claims subject to the rejection depend, requires administering a topical formulation of an IL-11 containing pharmaceutical composition. Keith does not describe a pharmaceutical solution of IL-11 that is topically applied. Rather, Keith describes only subcutaneous administration of IL-11 to treat mucositis, e.g., see Abstract and page 80, paragraph 3. Therefore, this reference does not describe all the features of the claimed invention.

In view of the foregoing comments, Applicants respectfully request reconsideration and withdrawal of the rejections for anticipation

Rejections under 35 USC 103(a)

Claims 1-4 and 11-35 are rejected as being unpatentable over Keith in view of U.S. Patent No. 4,808,613 (hereinafter, "the '613 patent"). Claim 2 has been cancelled. The rejection is traversed to the extent it is applied to the claims as amended.

In establishing a rejection for obviousness, the Examiner has the initial burden of establishing that the teachings of the applied art would have suggested the claimed invention to one of ordinary skill in the art and that such person would have had reasonable expectation of success. In re O'Farrell, 853 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). However, this suggestion must be in the prior art and not in the Applicants' disclosure. In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Claim 1, from which the remaining claims subject to the rejection depend, is drawn to a method of treating mucositis by administering a topical formulation of IL-11. As described above, Keith does not describe topical application of IL-11 for treating mucositis. The '613 patent describes the delivery of analogs of rebaccamycin, a small molecule antineoplastic compound, in various solid and liquid carriers. However, the '613 patent is completely silent about compositions that include therapeutic polypeptides, or compositions for topical delivery of therapeutic polypeptides.

As motivation for producing the claimed invention, the Examiner notes (paragraphs bridging pages 7 and 8):

One of ordinary skill would have been motivated with reasonable expectation of success to modify the methods of Keith et al. because Kaneko et al. teach pharmaceutical compositions comprising anti-tumor agents for therapeutic purposes.

However, no language is cited from either reference that would suggest that modifying each to produce the claimed invention would be desirable or likely to succeed. The Examiner points to no suggestion or motivation for producing Applicants' claimed invention in the cited references, or to an expectation of success by combining the cited references. For example, no explanation is provided about how the artisan would be motivated to make the claimed invention by replacing the small molecule antineoplastic agent rebaccamycin in the formulations described in Kaneko with the polypeptide IL-11 described in Keith, for the purpose of treating mucositis.

Instead, it appears the Examiner has improperly relied on Applicants' specification to find motivation for combining the references. Applicants teach in their specification that IL-11 is useful for treating mucositis (see pages 20-24 and 25-26, Examples 2 and 4). Applicants further teach various forms and means to deliver an IL-11-containing pharmaceutical composition (see page 12, line 13 through page 18, line 12).

In short, there are no teachings or suggestions in the applied references as to why one of ordinary skill in the art would combine them to arrive at Applicants' claimed invention. Rather, the only apparent reason discernible for combining the prior art of record is the Applicant's disclosure. Thus, the Examiner has engaged in impermissible hindsight to arrive at the conclusion that the claimed invention is obvious over Keith in view of the '613 patent. In re Fritch, 972 F.2d 1260, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983) cert. denied 469 U.S. 851 (1984) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no

prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher”).

Claims 1-4 and 11-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith, in view of the ‘613 patent and further in view of U.S. Patent No. 5,425,950 (hereinafter, “the ‘950 patent”). The rejection is traversed to the extent it is applied to the claims as amended.

The non-obviousness of claim 1, from which depends the other rejected claims, has been discussed above in view of the combination of Keith and the ‘613 patent.

The ‘950 patent is cited for describing immediate and sustained release of compositions (column 1, lines 48-67) as well as pharmaceutical compositions suitable for gastrointestinal tract and oral administration (column 3, lines 54-58). However, the Examiner points to no motivation or suggestion in this reference for producing the claimed invention. Thus, the ‘950 patent fails to overcome the deficiencies of Keith and the ‘613 patent.

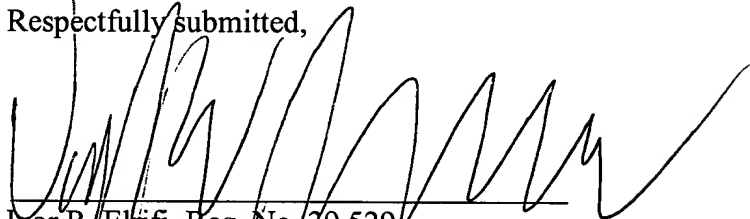
In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections for obviousness.

CONCLUSION

Applicants submit that the application is in condition for allowance, and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A petition for an extension of time and fee accompanies this response. The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the papers transmitted herewith, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 22058-522CON (GI-5238BA)).

Respectfully submitted,

A large, stylized handwritten signature in black ink, likely belonging to David E. Johnson, is written over a horizontal line.

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